Epidemiol. Infect. (2011), **139**, 1895–1901. © Cambridge University Press 2011
doi:10.1017/S0950268810003006

SHORT REPORT
Facemasks and intensified hand hygiene in a German household trial during the 2009/2010 influenza A(H1N1) pandemic: adherence and tolerability in children and adults

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(*Accepted 8 December 2010; first published online 7 January 2011*)

SUMMARY

Non-pharmaceutical interventions (NPI) such as facemasks and intensified hand hygiene may be effective in preventing influenza infections in households. It may be equally important that household members, especially children, can learn to use, maintain and tolerate these measures. We monitored adherence and tolerability of these NPI within a cluster-randomized trial in households with influenza index patients. We recruited 147 participants in 41 households, 39 (95%) out of 41 index patients were children (aged <14 years). In households assigned to wear facemasks, their use peaked on day 4 after symptom onset of the index patient at 73% and at 65% for children and adults, respectively. Mean daily frequency of hand disinfection in households assigned to intensified hand hygiene measures peaked at 7·7 (day 6) for children and at 10·1 (day 5) for adults. The majority of participants reported no problems with mask wearing. Data suggest that usage of NPI can be taught and that measures are well tolerated by adults and even sick children alike.

Key words: Adherence, influenza, non-pharmaceutical interventions.

In recent years, evidence has emerged suggesting that non-pharmaceutical interventions (NPI) such as surgical facemasks or intensified hand hygiene may be effective in preventing influenza transmission when used in households or university residence halls [1–3]. In addition to the effectiveness of these interventions, however, it seems equally important to understand which factors influence adherence and tolerability of NPI [4]. These two aspects are especially meaningful when considering the role of children in within-household transmission of influenza. Frequently, children introduce influenza into a household or – if previously healthy – they are more likely than adults to be infected by other household members [5, 6]. Use of NPI in children may thus be an important determinant in the prevention of influenza transmission in households, yet little is known about adherence and tolerability of NPI in children and adults.

Adherence to NPI in infectious diseases is influenced by factors that relate to (i) perceived susceptibility to the agent [in this case pandemic influenza A(H1N1) 2009], (ii) knowledge on transmission routes, (iii) perceived severity of the infection, (iv) self-perception especially in terms of health status, (v) expected benefits of a measure, (vi) barriers to adopting the measure and (vii) potential side-effects [7–9].

While the use of facemasks by the general public was not promoted actively in Germany during the 2009 influenza pandemic, attempts to raise public awareness for other NPI (especially intensified hand hygiene) had already been made during recent years

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and were intensified during the first months of the 2009 pandemic.

During the autumn/winter of 2009 we conducted a cluster-randomized intervention study on the effectiveness of facemasks and hand hygiene for the prevention of influenza transmission in households with influenza index patients. Within the framework of this study we also collected data on adherence and tolerability of these NPI, which we analysed with the following objectives: First, to measure the use of facemasks and the frequency of hand washing/disinfection in intervention as well as in non-intervention households; second, to compare adherence between index patients and household contacts as well as between children and adults; third, to identify frequency and reasons for non-adherence; and finally to investigate possible associations between attitudes/perceptions and behaviour.

The study was conducted in the city of Berlin, Germany, during the influenza season 2009/2010 and is going to be repeated in season 2010/2011. Results presented in this paper are based on data collected between November 2009 and January 2010.

Inclusion criteria for index patients were presentation at their general practitioner or paediatrician within 2 days of symptom onset, a positive rapid antigen test for influenza [which later had to be confirmed by real-time–polymerase chain reaction (RT–PCR)], age >2 years, and being the only case suffering from respiratory disease within their household during the 14 days preceding their illness.

Exclusion criteria for households were pregnancy, severely reduced health status, and HIV infection in the index patient or any household member as well as households with fewer than two members.

When household members developed fever, cough or sore throat and tested positive for influenza by RT–PCR they were considered secondary household cases.

After giving informed consent, households (as clusters) were randomized into one of three arms: (i) *Mask/Hygiene* (*MH*) *household*: the household was provided with surgical facemasks with earloops (Aérokyn Masques, LCH Medical Products, France) and alcohol-based hand rub (Sterillium™, Bode Chemie, Germany) together with written information on its correct use; (ii) *Mask* (*M*) *household*: the household was provided with surgical facemasks and information on their correct use, and (iii) *Control* (*C*) *household*: no masks or hand rub were provided. Randomization was performed at a ratio of 1:1:1. Recruiting physicians were blinded towards randomization. All participating households received general written information on infection prevention [10] and recommendations to sleep in a different room than the index patient, not to take meals with the index patient, etc. On the day of recruitment households received all necessary material and were instructed by telephone on how to use it (provisional implementation of the intervention). Trained study personnel visited the households no later than 2 days after symptom onset of the index case and demonstrated the interventions (full implementation of the intervention). Participants in the MH and M groups were asked to wear masks at all times except during the night when the index patient (or another member of the household with respiratory symptoms) was in the same room. Facemasks were to be changed regularly during the day. Participants of MH households were asked to always use the provided hand rub after direct contact with the index patient (or other symptomatic members of the household) or after having touched household items being used by the index patient and/or other symptomatic household members, as well as after coughing/sneezing, before meals, before preparing meals and when returning home.

The observation period of each household lasted for 8 days, starting on the day of symptom onset of the index patient (day 1). Households were visited on days 2, 3, 4, 6 and 8 (five times) or on days 3, 4, 6 and 8 (four times), depending on the day of recruitment. During these visits, nasal wash specimens (or, if these were not possible, nasal swabs) from all participants within the household were obtained and later analysed by RT–PCR.

All participants self-recorded symptoms in a daily monitoring questionnaire. Participants of the MH and M groups recorded daily adherence with facemasks in 'transmission-prone' situations, i.e. if they wore a mask 'never', 'sometimes', 'mostly' or 'always' when at least one ill household member and at least one healthy household member were in the same room. Participants of the MH households recorded the daily number of hand disinfections.

Household members developing fever, cough or sore throat in the course of study were asked to adopt the same preventive behaviour as the index patient until the end of the observation period.

An exit questionnaire conducted during a final home visit collected information on general perceptions of NPI, use of facemasks and hand rub during the observation period (including the actual amount

of intervention material used by households) as well as reasons for not wearing facemasks from all study participants. Used intervention material per household member was estimated by dividing the amount used per household by the number of household members. Problems with intensified hand hygiene were not addressed. Parents answered the questionnaires on behalf of their children.

Because of the large number of respiratory samples which we obtained during the study period participants received a reimbursement of €150. Children were defined as participants aged <14 years, all other participants were termed adults.

For statistical analysis of the data, we used Student's t test and one-way analysis of variance (ANOVA) for continuous variables with comparisons between two and three groups, respectively, and χ^2 test for categorical variables. All statistical tests were two-sided and $P<0{\cdot}05$ was considered statistically significant. Statistical tests were performed with Stata software version 11 (Stata Corporation, USA).

Ethics committee approval for the study was granted by the Ethics Committee of the Charité Universitätsmedizin Berlin (EA1/043/07).

We recruited 62 potential index cases with a positive rapid antigen test for influenza A. Seven of these had to be excluded before randomization, therefore 55 index patients and 156 household contacts were eligible for randomization. After random assignment, 14 (25%) out of 55 households had to be excluded for different reasons [onset of symptoms in a household contact on the same day as the index patient ($n=10$ households), non-confirmation of an initially positive (rapid) test for influenza via RT–PCR ($n=1$), refusal of further participation ($n=2$), unsettled child custody matters ($n=1$)].

Of the remaining 147 eligible participants from 41 households, 57 were from the MH group (17 index patients, 40 household contacts), 41 from the M group (11 index patients, 30 household contacts) and 49 from the C group (13 index patients, 36 household contacts). Mean age of index patients was 7·9 years [standard deviation (S.D.) $=3{\cdot}3$] and of household contacts 30·0 years (S.D. $=14{\cdot}2$). Thirty-nine (95%) of 41 index patients were children. Forty-nine per cent of index patients and 47% of household contacts were male. Age, sex, chronic illnesses, smoking and influenza vaccination rates were not significantly different across the study arms at baseline. A median of four people [interquartile range (IQR) 3–5] lived in each household, with a median of two children (IQR 1–2). The majority of household contacts (88/105, 84%) from all intervention groups did not sleep in the same room as the index patient, while only slightly more than half of all contacts did not share meals with the index patient (55/106, 55%). For both measures there were no significant differences between adult and child household contacts.

We visited 30 (73%) of 41 households within 48 h after symptom onset of the index case – the remaining 11 households were visited on the third day. Neither household size nor the timing of the home visits showed significant differences between study arms.

In the exit questionnaire 25 (89%) of 28 index patients and 62 (90%) of 69 household contacts from the combined MH and M groups reported wearing masks during the study period. After stratification of household contacts by age, 79% (11/14) of children and 93% (51/55) of adults wore masks. When analysing the use of facemasks in specific situations, we found that 81% (21/26) of index patients and 71% (49/69) of household members [64% (9/14) in child household contacts, 73% (40/55) in adult household contacts] wore a mask 'always' or 'most of the time' when in the same room with either a healthy or infected person, respectively. None of these differences were statistically significant. Sixty-two per cent (21/34) of healthy adult household members wore a mask when providing care for the infected person. Within the C group two (17%) out of 12 index patients and three (9%) out of 32 household contacts wore facemasks at some point during the study period.

The number of facemasks used per household member did not differ between the two intervention groups provided with facemasks (M, MH): participants of the M group used a median of 13 masks (IQR 7–20) compared to 15 masks (IQR 7–20) in participants of the MH group ($P=0{\cdot}6$).

Daily wearing of facemasks according to instructions was categorized as 'adherent' when the facemask was worn 'mostly' or 'always' during each day of the study period and otherwise as non-adherent. Analysis of daily adherence by age, irrespective of infection status, showed that the proportion of participants in the MH and M groups wearing a facemask after full implementation of the intervention [open symbols (○) in Fig. 1] reached about 60% by day 3 and remained above 50% until day 8 in children and above 45% in adults (Fig. 1). Although provisional implementation of the intervention led to a slight increase in adherence on day 2 [square symbols (■) in Fig. 1], it rose substantially only after interventions

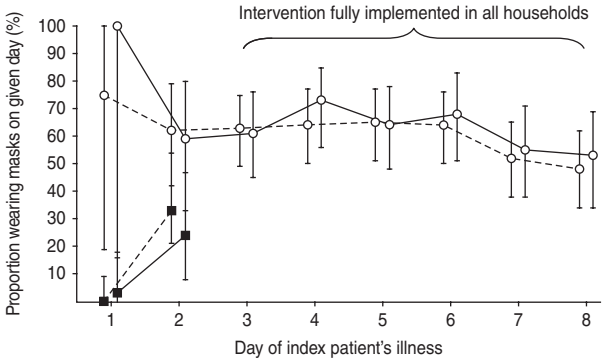

Fig. 1. Daily proportion and 95% confidence interval of wearing a facemask 'always' or 'most of the time' in transmission-prone situations, in participants assigned to groups wearing facemasks and practising intensified hand hygiene (MH) or only wearing facemasks (M), stratified by age. Symbols represent the proportion of participants wearing facemasks before (■) and after (○) the intervention was fully implemented in the households. Data of children (index or household contacts) are depicted by a continuous line, data of adults (index or household contacts) by a dashed line.

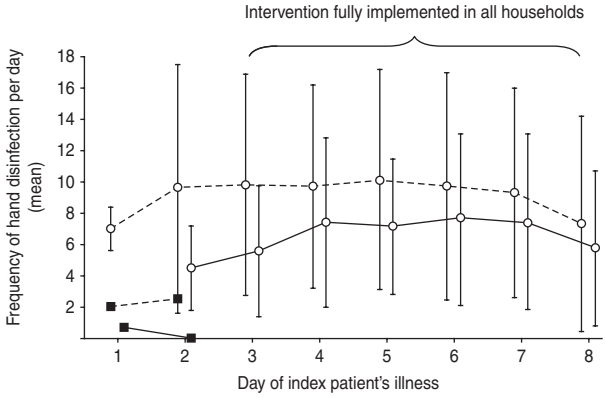

Fig. 2. Frequency of daily hand disinfection (mean ± standard deviation) in participants assigned to the MH group. Symbols represent the mean frequency of hand disinfection before (■) and after (○) the intervention was fully implemented in the households. Data of children (index or household contacts) are depicted by a continuous line, data of adults (index or household contacts) by a dashed line.

were fully implemented. There was neither a significant difference in facemask adherence between child index patients and child household contacts, nor between child household contacts and adult household contacts (data not shown).

The majority (51/85, 60%) of all participants in the MH and M groups did not report any problems when wearing facemasks. There were no significant differences between child index patients (13/24, 57%), child household contacts (8/13, 62%) and adult household contacts (30/47, 64%) (adult index patients were omitted here because only two of all index patients were at least 14 years old).

Of 12 index patients and 22 household contacts, respectively, who reported having removed their masks in transmission-prone situations, seven (58%) and five (23%) reported 'feeling hot' as the main reason ($P=0{\cdot}04$). Other problems mentioned less frequently were pain when wearing the mask [three (25%) index patients, two (9%) household contacts], and shortness of breath [one (8%) index patient, two (9%) household contacts].

During the exit interview participants were asked if they had washed/disinfected their hands less, equally, or more frequently during the 8 days of observation compared to before. In the MH, M and C groups, respectively, 88% (15/17), 73% (8/11) and 54% (7/13) of index patients ($P=0{\cdot}2$), and 92% (36/39), 66% (19/29) and 69% (25/36) of household contacts ($P=0{\cdot}02$) had washed their hands more frequently than before. Participants (index and contacts combined) of the MH group washed/disinfected their hands significantly more often during the study period compared to the time before than those of the M and C groups combined [51/56 (91%) *vs.* 59/89 (66%), $P=0{\cdot}007$]. Regarding the cleaning of hands in specific situations, the majority of participants in all intervention groups stated that they had performed hand hygiene before eating [70% (29/41) of index patients, 86% (90/105) of household contacts]. In other situations hands were cleaned (i.e. washed or disinfected) less frequently:

- 42% (17/41) of index patients did so 'always' or 'often' after coughing or sneezing [MH index patients only: 53% (9/17)],
- 64% (36/56) of household contacts after helping the ill person [MH household contacts only: 74% (17/23)],
- 31% (32/105) of household contacts after using household items being also used by the ill person [MH household contacts only: 43% (17/39)].

In MH group participants the mean frequency of daily hand disinfection over the whole study period was 7·6 (S.D. = 6·4) times per day for all participants and, when stratified by age, 6·0 (S.D. = 5·1) times per day for children and 8·6 times (S.D. = 7·0) per day for adults ($P=0{\cdot}1$). The median amount of hand rub used per household member was 87 ml (IQR 25–125 ml).

When considering each day individually (Fig. 2) daily frequency of hand disinfection was also higher

in adults than in children – irrespective of illness status. This difference was statistically significant on days 2 and 3 of the observation period. Figure 2 also gives information on hand disinfection frequency in intervention households before full implementation of these measures [square symbols (■) on days 1 and 2].

A large proportion of adult household contacts in the control and intervention groups perceived wearing facemasks (68/81, 84%) as well as intensified hand hygiene (69/83, 83%) as an effective means of preventing transmission of influenza. Proportions in the intervention groups (MH and M) were a little higher than in the control group, but not significantly so ['facemasks can prevent influenza transmission' – MH: 29/33 (88%); M: 19/21 (91%); C: 20/27 (74%); 'hand hygiene can prevent influenza transmission' – MH: 27/31 (87%); M: 18/22, (82%); C: 24/30 (80%)].

Use of a facemask and practising intensified hand hygiene were more strongly influenced by the assignment to the respective intervention groups than by the participant's perceptions of their effectiveness. In participants of the C and M groups (who were not specifically asked to wash/disinfect hands more frequently) the perception that intensified hand hygiene may prevent transmission of influenza infections was significantly associated with (self-reported) increased frequency of hand washing/disinfection during the observation period (odds ratio 25·6, 95% confidence interval 2·9–230·3, $P=0{\cdot}004$).

We present data on adherence and tolerability of facemasks and hand hygiene taken from a cluster-randomized trial on the effectiveness of NPI for the prevention of influenza transmission in households. After instructions were given to participants, daily use of facemasks increased rapidly (MH, M groups) and participants also indicated intensification of hand hygiene (MH group). The effects were observed both in children and adults although self- (or parent-)-reported frequency of hand disinfection was slightly higher in adults compared to children. The increased level of facemask use and hand hygiene was maintained throughout the 8-day study period. Facemasks were well tolerated, even in index cases (consisting mostly of children), and the main side-effect was feeling hot. In both intervention groups and the C group the majority of participants perceived the two measures as effective against transmission of influenza (within households). General measures of infection prevention that were recommended to all households were observed by most household contacts (not sleeping in the same room) and about half of household contacts (not eating together).

In recent years, three studies examining the effectiveness of NPI on household (or dormitory) level have been published [1–3]. Although the main focus of these studies was the effectiveness of interventions, adherence and in some cases tolerability of measures were also investigated. Of these three studies two reported on adherence to wearing facemasks [2, 3], which was lower compared to our study. Furthermore, we noted substantially increasing adherence after participants had received detailed instructions during a first household visit (Figs 1 and 2). Finally, in our study adherence to mask wearing was sustained at a high level until day 7 of the study period, whereas it had already begun to decline around day 3 in the other studies cited above [2, 3].

There are several possible reasons for the observed differences, the first being that the present study was conducted during the 2009 influenza pandemic. In the past, low adherence to NPI was expected to rise in the case of an influenza pandemic due to higher perceptions of severity and threat posed by the illness, both of which are known to strongly influence health-related behaviour [7, 8]. A second reason is that the monetary incentive (given because of the high number of respiratory samples obtained during the study period) and the repeated home visits by study personnel may have motivated participants, but may have also made them feel obliged to give answers that they assumed to be 'desired' by the study personnel.

We did not find differences in adherence between index patients and household contacts or between children and adults. The first aspect is in contrast to Cowling *et al.* where index patients showed significantly greater adherence than household contacts [2], while the second aspect has not been examined in other studies. We regard this aspect as important because children play a major role in transmission of influenza within households and are more susceptible towards influenza infection in general [5, 6]. It is noteworthy that we did not observe a higher rate of problems with the wearing of facemasks (potentially leading to removal of masks) in children compared to adults.

Taken together, these results indicate, that wearing a facemask during a defined period of time and within transmission-prone situations is feasible and tolerable for adults and (sick) children alike.

In our study cohort, 90% of participants from the MH group and about 70% each from the M and C

groups reported that they had washed or disinfected their hands more frequently during the illness period of their household's index patient than previously. The large proportion of participants in the M and C groups practising intensified hand hygiene requires explanation as these two groups were not specifically asked to modify their behaviour. Hand hygiene was promoted through television spots, leaflets and other means during the 2009 influenza pandemic and even earlier, so that the role of hand hygiene in the prevention of influenza may have become common knowledge and practice. As 'washing one's hands' is also an intervention perceived as a typical daily behaviour by the general public, participants 'only' needed to increase frequency and be more vigilant in situations where hand hygiene may be beneficial [11]. As noted above, it is also possible that participants provided responses which they assumed to be desirable or 'correct'.

Considering the daily frequency of hand hygiene measures in the MH group, a mean number of hand disinfections of about 8 times a day by adults can be compared to another intervention study in university students during seasonal influenza [1], where the group assigned to hand hygiene had washed and disinfected their hands on average six times and five times, respectively. Data from a cross-sectional telephone survey during the early pandemic phase in the UK indicated that people washed their hands about 11 times per day [12].

Although the general hand hygiene frequency of children was lower compared to adults, our data indicate that children can be educated to clean their hands more frequently and sustain that level over a number of days. This is in accord with studies suggesting that hand hygiene can be taught and the effect sustained even in elementary school children [13, 14].

The majority of participants expressed the belief that facemasks can prevent influenza transmission in the household. This may seem surprising, as this measure is not very common in Germany and was not officially recommended by public health authorities during the 2009 pandemic. Nevertheless, experience showed that although the actual wearing of facemasks in non-intervention households was low (below 20% in index and household contacts, respectively) this positive attitude allowed a rapid increase in the use of masks when these were provided and their usage explicitly encouraged.

The majority of participants in our study also perceived hand hygiene as effective in the prevention of influenza. This is comparable to data of other studies conducted during the 2009 pandemic [7, 12] and it also underlines that public health efforts to advocate hand hygiene in recent years may have been successful.

This study has several limitations. Although we attempted to adapt the design of this study to other similar studies regarding the observation period of households or the type of questions asked, other factors may have influenced behaviour which were beyond our control, such as societal differences (especially attitudes towards masks or hygiene in the general public) or the timing of the study (seasonal *vs.* pandemic influenza). These differences impair comparability between our study and others to a certain extent. A further limitation is that data are self-reported and that questions about perceptions were only asked within the questionnaire conducted during the final home visit. Perceptions may thus have been influenced by the interventions. Furthermore, both behaviour and perceptions may have been influenced by monetary incentives as well as by frequent household visits of study personnel. However, other studies have also been conducted using frequent household visits so this limitation should not represent a major problem in comparability of results. As a lot of our participants were children, their questionnaires had to be answered by their parents, who may have partially projected their own behaviour or that expected of their children into the answers 'for' their children. We therefore restricted the analysis of perceptions towards NPI and their association with behaviour to adults only.

In conclusion, we were able to show that adults and children alike can be educated to wear masks and increase hand hygiene frequency. Moreover, children accepted the wearing of masks – even when ill – at a frequency comparable to adults. Positive attitudes towards both NPI may have facilitated implementation of these measures. Our findings do not indicate major problems in terms of acceptability, adherence and tolerability of NPI in households – supporting the need to strengthen the evidence for the effectiveness of these measures.

ACKNOWLEDGEMENTS

This study was financially supported by the German Federal Ministry of Health.

DECLARATION OF INTEREST

None.

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